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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,400	07/20/2001	Lee M. Nadler	50059/007002	7028

7590

06/26/2006

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EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,400

Applicant(s)

NADLER ET AL.

Examiner

Amy E. Juedes, Ph.D.

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy E. Juedes, Group Art Unit 1644, Technology Center 1600.

2. Applicant's election of group VI, claims 18-19 and 44, in the reply filed on 4/24/06 is acknowledged. However, upon reconsideration, the restriction requirement issued on 3/27/06 is vacated. The following is a new requirement for restriction.

3. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 11-15, 28-31, 38-41, drawn to a method of treating a patient that comprises or is at risk of comprising a cell that expresses hTERT, comprising administering to said patient a cytotoxic T lymphocyte that kills said cell in an hTERT-specific, major histocompatibility complex-restricted fashion.

Group II, claims 5-6, 11-15, 32-33 and 38-41, drawn to a method of treating a patient that comprises or is at risk of comprising a cell that expresses hTERT, comprising administering to said patient an antigen presenting cell that activates cytotoxic T lymphocyte that kills said cell in an hTERT-specific, major histocompatibility complex-restricted fashion.

Group III, claims 7-8, 11, 13-15, 34-35, 38 and 40-41, drawn to a method of treating a patient that comprises or is at risk of comprising a cell that expresses hTERT, comprising administering to said patient hTERT or a peptide of hTERT that binds to a major histocompatibility complex molecule and that activates cytotoxic T lymphocyte that kills said cell in an hTERT-specific, major histocompatibility complex-restricted fashion.

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Group IV, claims 9-11, 13-15, 36-38 and 40-41, drawn to a method of treating a patient that comprises or is at risk of comprising a cell that expresses hTERT, comprising administering to said patient a nucleic acid molecule encoding hTERT or a peptide of hTERT that binds to a major histocompatibility complex.

Group V, claims 16-17 and 42-43, drawn to a method of assessing the level of immunity of a patient to hTERT or a peptide of hTERT that binds to a major histocompatibility complex molecule, comprising measuring the level of cytotoxic T lymphocytes specific for hTERT or peptide of hTERT in a sample from patient.

Group VI, claims 18-19 and 44, drawn to the universal tumor-associated antigen, hTERT, or a peptide thereof that binds to a major histocompatibility complex molecule.

Group VII, claims 20 and 45, drawn to an ex vivo generated cytotoxic T lymphocyte that specifically kills a cell expressing hTERT in a specific, major histocompatibility complex-restricted fashion.

Group VIII, claims 21 and 46, drawn to an ex vivo generated antigen presenting cell that presents a peptide of an hTERT in the context of a major histocompatibility complex molecule.

Group IX, claims 22-27, drawn to a method for identifying a universal tumor associated antigen, comprising analyzing one or more databases to identify a gene, using a computer-run algorithm to identify an amino acid sequence and synthesizing an immunogen, testing the ability of said immunogen to stimulate a major histocompatibility complex-restricted cytotoxic T lymphocyte response.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is further required to:

elect a specific hTERT peptide from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2 (if group I-IV or VI is elected),

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elect a specific antigen presenting cell selected from the groups consisting of a dendritic cell or a CD40 activated B cell (if group I-II or IX is elected),

and list all Claims readable thereon including those subsequently added. Currently claims 4, 6, 7-8, 9-10, 13, and 18, and 44 are generic with respect to an hTERT peptide, and claims 4-6, 26, and 31-33 are generic with respect to an antigen presenting cell.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The inventions listed as groups I-IX and the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The invention of Group VI, drawn to a universal tumor-associated antigen or a peptide thereof that binds to a major histocompatibility complex molecule, has no special technical feature that defines the contribution over the prior art of Kawashima et. al. (IDS)

Kawashima et. al. disclose peptides from HER-2/neu antigen (i.e. universal tumor-associated antigen) binding to HLA-A2.1.

8. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. Accordingly, groups I-IX are not so linked as to form a single general inventive concept and restriction is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

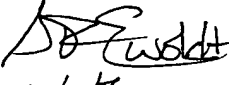
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy Juedes, Ph.D.  
Patent Examiner  
Technology Center 1600  
June 5, 2006

  
6/10/06  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**